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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,906	12/21/2005	Miroslav Patek	281642US0XPCT	1503
22850 7590 01/12/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER DESAI, ANAND U	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 01/12/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/561,906	<b>Applicant(s)</b> PATEK ET AL.	
	<b>Examiner</b> ANAND U. DESAI	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-31 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14-18, 20, 22-27, and 29 is/are rejected.
- 7) ☒ Claim(s) 13, 19, 21 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to the amendment filed on September 30, 2008. Claims 1-11 have been cancelled. New claims 12-31 have been added.

2. Newly submitted claims 30 and 31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are drawn to a distinct method of using a polypeptide to prepare an enantiomer-enriched branched-chain amino acid, while the pending claims are drawn to an isolated nucleic acid molecule, a vector, a host cell, and a method of making a polypeptide using the host cell.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30 and 31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 12-29 are currently pending and are under examination.

4. Any objections and rejections not recited below are hereby withdrawn.

### **Withdrawal of Rejections**

5. The rejection of claim 8 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process is withdrawn based on the cancellation of the claim.

6. The rejection of claims 8 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.

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7. The rejection of claims 1 and 3-6 under 35 U.S.C. 102(b) as being anticipated by Livshits et al. (US 2002/0037562 A1) is withdrawn based on the amendment to the claims.

## **Pending Rejections**

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 12, 16, 18-20, 22-27, and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected for failing to disclose the structure to function correlation of a genus of isolated nucleic acid sequences that have acetohydroxy acid synthetase (AHAS) activity. The disclosure does not describe a representative number of species of the nucleic acid sequences that encompass a genus of 70% homology to SEQ ID NO: 1 or SEQ ID NO: 3.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008,

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1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two

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chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claim 16 is a broadly generic to all possible nucleic acid sequence that have 70% homology/identity to the claims. The possible variations are enormous. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure beyond those disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide representative members within the genus of 70% homology.

While having written description of SEQ ID NO: 1 or SEQ ID NO: 3 identified in the specification tables and/or examples, the specification is devoid of any genus encompassed by 70% homology that qualify for the functional characteristics claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed

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that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 12, 14-18, 20, 22, 25, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakagawa et al. (US 2002/0197605 A1; previously cited).

Nakagawa et al. disclose an isolated nucleic acid that can hybridize with the nucleic acid identified as SEQ ID NO: 1, a vector comprising the nucleic acid, and a transformed host cell comprising the isolated nucleic acid (see claims 1-13 and sequence alignment below). A sequence having 96.9% identity would hybridize at high stringency as currently claimed.

RESULT 3  
US-09-738-626-1  
; Sequence 1, Application US/09738626  
; Publication No. US20020197605A1  
; GENERAL INFORMATION:  
; APPLICANT: NAKAGAWA, SATOSHI  
; APPLICANT: MIZOGUCHI, HIROSHI

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; APPLICANT: ANDO, SEIKO  
; APPLICANT: HAYASHI, MIKIRO  
; APPLICANT: OCHIAI, KEIKO  
; APPLICANT: YOKOI, HARUHIKO  
; APPLICANT: TATEISHI, NAOKO  
; APPLICANT: SENOH, AKIHIRO  
; APPLICANT: IKEDA, MASATO  
; APPLICANT: OZAKI, AKIO  
; TITLE OF INVENTION: NOVEL POLYNUCLEOTIDES  
; FILE REFERENCE: 249-125  
; CURRENT APPLICATION NUMBER: US/09/738,626  
; CURRENT FILING DATE: 2000-12-18  
; PRIOR APPLICATION NUMBER: JP 99/377484  
; PRIOR FILING DATE: 1999-12-16  
; PRIOR APPLICATION NUMBER: JP 00/159162  
; PRIOR FILING DATE: 2000-04-07  
; PRIOR APPLICATION NUMBER: JP 00/280988  
; PRIOR FILING DATE: 2000-08-03  
; NUMBER OF SEQ ID NOS: 7059  
; SOFTWARE: PatentIn ver. 3.0  
; SEQ ID NO 1  
; LENGTH: 3309400  
; TYPE: DNA  
; ORGANISM: Corynebacterium glutamicum  
US-09-738-626-1

Query Match 96.9%; Score 503; DB 3; Length 3309400;  
Best Local Similarity 98.1%; Pred. No. 8.2e-151;  
Matches 509; Conservative 0; Mismatches 10; Indels 0; Gaps  
0;

Qy 1 ATGGTCAATTCTGACGTCACCCGCCACATCCTGTCCGTACTCGTTCAGGACGTAGACGAT 60  
|||||  
Db 1340025 ATGGCTAATTCTGACGTCACCCGCCACATCCTGTCCGTACTCGTTCAGGACGTAGACGGA  
1340084

Qy 61 GACTTTTCCCGCGTATCAGGTATGTTACCCGACGCGCATTCAACCTCGTGTCCCTCGTG 120  
|  
Db 1340085 ATCATTTCCTCCGCGTATCAGGTATGTTACCCGACGCGCATTCAACCTCGTGTCCCTCGTG  
1340144

Qy 121 TCTGCAAAGACCGAAACACACGGCATCAACCGCATCACGGTTGTTGTCGACGCCGACGAG 180  
|||||  
Db 1340145 TCTGCAAAGACCGAAACACACGGCATCAACCGCATCACGGTTGTTGTCGACGCCGACGAG  
1340204

Qy 181 CTCAACATTGAGCAGATCAACAAGCAGCTCAACAAGCTGATCCCCGTGCTCAAAGTCGTG 240  
|||||  
Db 1340205 CTCAACATTGAGCAGATCACCAGCAGCTCAACAAGCTGATCCCCGTGCTCAAAGTCGTG  
1340264

Qy 241 CGACTTGATGAAGAGACCACTATCGCCCGCGCAATCATGCTGGTTAAGGTCTCTGCGGAC 300  
|||||



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Db 1340265 CGACTTGATGAAGAGACCACTATCGCCCGCGCAATCATGCTGGTTAAGGTCTCTGCGGAC  
1340324

Qy 301 AGCACCAACCGTCCGCAGATCGTCGACGCCGCGAACATCTTCCGCGCCCGAGTCGTCGAC 360

|||||  
Db 1340325 AGCACCAACCGTCCGCAGATCGTCGACGCCGCGAACATCTTCCGCGCCCGAGTCGTCGAC  
1340384

Qy 361 GTGGCTCCAGACTCTGTGGTTATTGAATCCACAGGCACCCCAGGCAAGCTCCGCGCACTG 420

|||||  
Db 1340385 GTGGCTCCAGACTCTGTGGTTATTGAATCCACAGGCACCCCAGGCAAGCTCCGCGCACTG  
1340444

Qy 421 CTTGACGTGATGGAACAATTTCGAAATCCGCGAACTGATCCAATCCGGACAGATTGCACTC 480

|||||  
Db 1340445 CTTGACGTGATGGAACCAATTTCGAAATCCGCGAACTGATCCAATCCGGACAGATTGCACTC  
1340504

Qy 481 AACCGCGGTCCGAAGACCATGGCTCCGGCCAAGATCTAA 519

|||||  
Db 1340505 AACCGCGGTCCGAAGACCATGGCTCCGGCCAAGATCTAA 1340543

### *Claim Objections*

12. Claims 13, 19, 21, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 4, 2009

/ANAND U DESAI/

Primary Examiner, Art Unit 1656